MAR 14 2012

K 102189

510(k) SUMMARY

1.0 Submitter:

Name: Latexx Manufacturing Sdn. Bhd.
Address: Lot 18374, Kamunting Industrial Estate
34600 Taiping, Perak
Malaysia
Phone: 605 891 1111
Fax: 605 829 5590
Contact Person: Ooi Loon Seng (Madam)

Date of Preparation: February 10, 2012

2.0 Name of Device:

Powder-Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim

Common Name: Examination Gloves

Classification Name: Patient Examination Gloves, Specialty Chemotherapy (21 CFR 880.6250 Product Code LZC)

510(k) Number: K102189

3.0 Legally Marketed Device to Which Equivalence is being Claimed:

Primary Predicate:
Cardinal Health Esteem Tru-Blu Stretchy Nitrile Exam Gloves
510(k) Number: K032444

Additional Predicate:
Powder-Free Blue Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim
510(k) Number: K022765

4.0 Description of the Device:

Powder-Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim, meeting all the requirements of ASTM standards D6319-10 and ASTM D6124-06. The gloves are non-sterile, single-use, disposable devices.

5.0 Indications for Use:

The Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim is a specialty medical glove which is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between examiner and patient. In addition these gloves are worn to protect the wearer against exposure to chemotherapy drugs. Tested chemotherapy drugs are as follows:

Test Chemical and Concentration	**Average Breakthrough Detection Time (minutes)**
Cisplatin, 1.0 mg/ml	≥ 240
Cyclophosphamide (Cytoxan), 20.0 mg/ml	≥ 240
Cytarabine, 100 mg/ml	≥ 240
Cytovene, 10 mg/ml	≥ 240
Dacarbazine (DTIC), 10.0 mg/ml	≥ 240
Docetaxel, 10.0 mg/ml	≥ 240
Doxorubicin Hydrochloride, 2.0 mg/ml	≥ 240
Etoposide (Toposar), 20.0 mg/ml	≥ 240
Fluorouracil, 50.0 mg/ml	≥ 240
Ifosfamide, 50.0 mg/ml	≥ 240
Irinotecan Hydrochloride, 20 mg/ml	≥ 240
Mechlorethamine HCl, 1.0 mg/ml	≥ 240
Methotrexate, 25 mg/ml	≥ 240
Mitomycin C, 0.5 mg/ml	≥ 240
Mitoxantrone, 2 mg/ml	≥ 240
Oxaliplatin, 5mg/ml	≥ 240
Paclitaxel (Taxol), 6.0 mg/ml	≥ 240
ThioTEPA	75.8
Vincristine Sulfate, 1.0 mg/ml	≥ 240
Vinorelbine, 10 mg/ml	≥ 240
Low Permeation Time (minutes) Carmustine (BCNU), 3.3 mg/ml	1.7

Please note that the following drug has an extremely low permeation time:
Carmustine (BCNU) 1.7 (mins)

6.0 Summary of Technological Characteristics of the Device:

Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim have the following technological characteristics compared to ASTM or equivalent standards:

Characteristics	**Standard**	**Device Performance**
Dimensions	ASTM D6319-10	Meets standard requirements
Physical Properties	ASTM D6319-10	Meets standard requirements
Thickness	ASTM D6319-10	Meets standard requirements
Biocompatibility	Primary Skin Irritation Study (ISO 10993-0:2002E)	Passes (Not a primary skin irritant)
	Dermal Sensitization (ASTM-F 720-81)	Passes (Not a contact sensitizer)
Watertight – 1000 ml (Freedom from Holes)	21 CFR 800.20	Passes
Resistance to Permeation by Chemotherapy Drugs	ASTM D6978-05	Meets standard requirements

Latexx Manufacturing "Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim" demonstrated the following breakthrough detection times when tested according to ASTMD6978-05

Test Chemical and Concentration	**Average Breakthrough Detection Time (minutes)**
Cisplatin, 1.0 mg/ml	≥ 240
Cyclophosphamide (Cytoxan), 20.0 mg/ml	≥ 240
Cytarabine, 100 mg/ml	≥ 240
Cytovene, 10 mg/ml	≥ 240
Dacarbazine (DTIC), 10.0 mg/ml	≥ 240
Docetaxel, 10.0 mg/ml	≥ 240
Doxorubicin Hydrochloride, 2.0 mg/ml	≥ 240
Etoposide (Toposar), 20.0 mg/ml	≥ 240
Fluorouracil, 50.0 mg/ml	≥ 240
Ifosfamide, 50.0 mg/ml	≥ 240
Irinotecan Hydrochloride, 20 mg/ml	≥ 240
Mechlorethamine HCl, 1.0 mg/ml	≥ 240
Methotrexate, 25 mg/ml	≥ 240
Mitomycin C, 0.5 mg/ml	≥ 240
Mitoxantrone, 2 mg/ml	≥ 240
Oxaliplatin, 5mg/ml	≥ 240
Paclitaxel (Taxol), 6.0 mg/ml	≥ 240
Thiotepa	75.8
Vincristine Sulfate, 1.0 mg/ml	≥ 240
Vinorelbine, 10 mg/ml	≥ 240
Low Permeation Time (minutes) Carmustine (BCNU), 3.3 mg/ml	1.7

7.0 Substantial Equivalence Based on Assessment of Non-Clinical Performance Data:

Comparison to Predicate and Non-Clinical Testing – The subject device (Powder-Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim) compares favorably to the predicate device (Cardinal Health Esteem Tru-Blu Stretchy Nitrile Exam Gloves) as indicated in the tabulated summaries to follow.

Substantial Equivalence Comparison of Indications for Use

The Indications for Use statements for the subject nitrile gloves and the cited predicate, as listed below, are substantially equivalent (SE).

Indications for Use – Subject Device:

Powder-Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim

The Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim is a specialty medical glove which is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between examiner and patient. In addition these gloves are worn to protect the wearer against exposure to chemotherapy drugs. Tested chemotherapy drugs are as follows:

Test Chemical and Concentration	Average Breakthrough Detection Time (minutes)
Cisplatin, 1.0 mg/ml	≥ 240
Cyclophosphamide (Cytoxan), 20.0 mg/ml	≥ 240
Cytarabine, 100 mg/ml	≥ 240
Cytovene, 10 mg/ml	≥ 240
Dacarbazine (DTIC), 10.0 mg/ml	≥ 240
Docetaxel, 10.0 mg/ml	≥ 240
Doxorubicin Hydrochloride, 2.0 mg/ml	≥ 240
Etoposide (Toposar), 20.0 mg/ml	≥ 240
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Irinotecan Hydrochloride, 20 mg/ml	≥ 240
Mechlorethamine HCl, 1.0 mg/ml	≥ 240
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ThioTEPA	75.8
Vincristine Sulfate, 1.0 mg/ml	≥ 240
Vinorelbine, 10 mg/ml	≥ 240
Low Permeation Time (minutes)Carmustine BCNU), 3.3 mg/ml	1.7

Please note that the following drug has an extremely low permeation time: Carmustine (BCNU) 1.7 (mins)

Indications for Use – Predicate Device: ***Cardinal Health Esteem Tru-Blu Stretchy Nitrile Gloves (Nitrile Powder-Free Examination Gloves with Lotion Coating, Blue with Use for Chemotherapy)*** **Cardinal Healthcare Corporation K032444)**	These examination gloves are disposable devices intended for medical purposes that are worn on the examiner's hands or fingers to prevent contamination between patient and examiner. In addition, these gloves are worn to protect the wearer against exposure to chemotherapy drugs.

Comparisons of non-clinical biocompatibility and engineering bench tests are included in the summary table below.

Substantial Equivalence Comparison Table – Engineering and Bench Testing

	Subject Device ***Powder-Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim***	**Predicate Device** ***Cardinal Health Esteem Tru-Blu Stretchy Nitrile Gloves (Nitrile Powder-Free Examination Gloves with Lotion Coating, Blue with Use for Chemotherapy)*** **Cardinal Healthcare Corporation K032444)**	**Substantial Equivalence (SE)?**
Chemotherapy Permeation Standard	Meets ASTM D6978-05	Meets ASTM D6978-05	Yes
Design Specifications & Glove Performance	Meets ASTM D6319-10: -Tensile Strength ≥ 14MPa (≥14MPa per Standard) -Elongation ≥400% (≥400% per Standard)	Meets ASTM D6319-00: -Tensile Strength 19Mpa (≥14 MPa per Standard) -Elongation 533% (≥400% per standard)	Yes
Freedom from Holes	Meets Requirements per 21CFR800.20: Gloves Free of Holes at quality level of AQL 1.5 (AQL 2.5 required per standard)	Meets Requirements per 21CFR800.20: Gloves Free of Holes at quality level of AQL 1.5 (AQL 2.5 required per standard)	Yes
Glove Thickness and Length	Meets ASTM D6319-10: -Palm Thickness of ≥0.10 mm -Finger Thickness ≥0.10 mm -Length ≥270 mm	Meets ASTM D6319-10: -Palm Thickness average 0.10 mm -Finger Thickness average 0.13 mm -Length average 246 mm	Yes
Materials	Flexible Nitrile	Flexible Nitrile	Yes

Substantial Equivalence Comparison Table – Engineering and Bench Testing (continued)

	Subject Device *Powder-Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim*	**Predicate Device** *Cardinal Health Esteem Tru-Blu Stretchy Nitrile Gloves (Nitrile Powder-Free Examination Gloves with Lotion Coating, Blue with Use for Chemotherapy)* **Cardinal Healthcare Corporation K032444)**	**Substantial Equivalence (SE)?**
Color	Synthetic Glove with embedded BLUE Biocompatible Colorant	Synthetic Glove with embedded BLUE Biocompatible Colorant	Yes
Technology of Glove Design, i.e. Coatings and/or Donning Aid	Ambidextrous; Inner Glove Surface Chlorine Treated to Facilitate Donning; Fingertips Textured to Improve Tactility and Grip	Ambidextrous; Lotion Coating on Inner Surface as Donning Aid: Outer Surface Textured to Improve Grip	Yes
Biocompatibility	Passes tests for : -Primary Skin Irritation -Dermal Sensitization	Passes tests for: -Primary Skin Irritation -Dermal Sensitization	Yes
Powder-Free	Meets Applicable Definition for Powder Free; ≤ 2 mg per glove	Meets Applicable Definition for Powder Free; ≤ 2 mg per glove	Yes
Sterility	Not Applicable: Non-Sterile	Not Applicable: Non-Sterile	Yes

Summary of Differences and Comparison of Safety and Effectiveness – The subject device differs from the predicate:

Difference in Donning Aid: The predicate device has an inner surface coated with lotion, and the subject device has a chlorine treated inner surface. Both the lotion coating and chlorine treatment serve as donning aids. Therefore, both gloves are functionally equivalent with regard to ease of user donning, and may be used to effectively keep users safe from exposure to chemotherapeutic agents.

Difference in Colorant: Latexx Manufacturing incorporates medical grade colorant into the subject device. The subject device has been tested and shown to function as an effective barrier to chemotherapeutic agents. The subject device has also passed biocompatibility tests for skin irritation and dermal sensitization; the subject gloves are non-toxic and may safely contact either users or patients.

8.0 Animal Testing:
No animal testing were required to demonstrate substantial equivalence.

9.0 Substantial Equivalence Based on an Assessment of Clinical Performance Data:
A clinical study was not conducted on the subject or predicate devices.

10.0 Conclusion:

"Powder-Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim" produced by Latexx Manufacturing Sdn. Bhd. are as safe and effective as the predicate device. The subject device has been tested against the applicable ASTM standards listed above, and meets the requirements set forth in those standards. Additional specific comparisons show the subject device substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Latexx Manufacturing Sdn. Bhd.
C/O Mr. Neil Burris
Regulatory Affairs Consultant
Reglera, LLC
11925 West 1-70 Frontage Road North, Suite 900
Wheat Ridge, Colorado 80033

MAR 14 2012

Re: K102189
Trade Name: Powder-Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim
Regulation Number: 21 CFR 880. 6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZC
Dated: February 27, 2012
Received: March 14, 2012

Dear Mr. Burris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898.. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97).. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Applicant: **LATEXX MANUFACTURING SDN. BHD.,**
LOT 18374, Kamunting Industrial Estate,
34600 Taiping, Perak, Malaysia

510(k) Number: K102189

Device Name: **POWDER FREE NITRILE EXAMINATION GLOVES TESTED FOR USE WITH CHEMOTHERAPY DRUGS LABELING CLAIM**

Indications For Use:

The Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim is a specialty medical glove which is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between examiner and patient. In addition these gloves are worn to protect the wearer against exposure to chemotherapy drugs. Tested for use with chemotherapy drugs. Tested chemotherapy drugs are as follows:

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Carmustine (BCNU) 1.7 (mins)

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter X
Per 21 CFR 801.109

Elizabeth F. Claverie-Williams

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102189